

CLAIMS

Please amend the claims as shown in the attached claim listing, which replaces all previous claim listings.

1. (Currently Amended) An implantable valve for a bodily passage of tubular shape, comprising:

a self-expanding support frame configured for expansion to conform to a wall of the bodily passage, said support frame having a plurality of bends, said plurality of bends configured to provide outward radial force for expansion of said self-expanding frame to anchor the implantable valve to the wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

a plurality of leaflets, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one other leaflet of the plurality of leaflets,

the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the plurality of leaflets includes an attachment extending along at least selected ones of the side elements such that the outer edge is adapted to resiliently and sealingly engage the wall of the bodily passage

along said path, wherein said attachment includes an amount of the outer edge of the leaflet wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding side element, each leaflet extending along said bodily passage away from the inner edges thereof in said second direction to form a curved structure for trapping fluid against the inner wall of the bodily passage in response to fluid flow in said second direction so as to cause said inner edges of said leaflets to engage one another sufficiently to restrict fluid flow in said second direction; and

wherein the implantable valve further includes at least one barb to anchor the implantable valve to the wall of the bodily passage.

2. (Previously Amended) The implantable valve of claim 1, wherein at least a portion of the body of the leaflet being flexible at least proximate the inner edge thereof.

3. (Canceled)

4. (Previously Amended) The implantable valve of claim 1 wherein the outer edges of the plurality of leaflets include overhanging material, the overhanging material extending beyond the frame to which the plurality of leaflets are attached.

5. (Previously Amended) The implantable valve of claim 1 wherein said frame comprises wire to and around which the bodies of the leaflets are secured.

6. (Previously Amended) The implantable valve of claim 1 wherein the plurality of leaflets includes two leaflets such that when the frame is substantially flattened, it assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.
7. (Currently Amended) The implantable valve of claim 1 ~~3~~ wherein the body and the frame of each leaflet comprises an integral, one-piece member.
8. (Currently Amended) The implantable valve of claim 7 ~~4~~ wherein said integral, one-piece member is molded into a generally flat shape.
9. (Original) The implantable valve of claim 7 wherein said integral, one-piece member is molded into a serpentine shape.
10. (Previously Amended) The implantable valve of claim 1 wherein the plurality of leaflets comprises an extracellular collagen matrix.
11. (Previously Amended) The implantable valve of claim 10 wherein the extracellular collagen matrix includes small intestinal submucosa.
12. (Currently Amended) The implantable valve of claim 1 comprising a pair of opposing ~~two~~ leaflets.
13. (Original) The implantable valve of claim 1 wherein the frame is adapted to assume a plurality of configurations, the plurality of configurations includes a

generally flat configuration, whereby the frame in the generally flat configuration is generally diamond-shaped.

14. (Canceled)

15. (Canceled) The implantable valve of claim 1 further including at least one barb to anchor the implantable valve to the wall of the bodily passage.

16. (Original) The implantable valve of Claim 15 wherein the at least one barb is integral projection extending from the frame.

17 - 54 (Canceled)

55. (Previously Amended) An implantable valve for a bodily passage of tubular shape, comprising:

- a support frame configured for expansion to conform to a wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

- a plurality of leaflets comprising an extracellular collagen matrix material, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one other leaflet of the plurality of leaflets,

- the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and

further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to directly engage the wall of the bodily passage therearound and provide ingrowth of adjacent native tissue into the extracellular collagen matrix material, wherein the outer edge of each one of the plurality of leaflets is wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding side element; and

wherein the implantable valve includes at least one barb to anchor the implantable valve to the wall of the bodily passage.

56. (Previously Presented) The implantable valve of claim 55 wherein the collagen matrix material comprises submucosal tissue.

57. (Previously Presented) The implantable valve of claim 55 wherein the collagen matrix material comprises small intestinal submucosa.

58. (Previously Presented) An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the plurality of legs terminating at a second end of the implantable valve opposite the first end such that the plurality of legs generally

assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage, and wherein the outer edge is wrapped around a corresponding leg to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding leg;

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction and seal against one another to restrict fluid flow in said second direction; and

wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane; and

wherein the implantable valve includes at least one barb to anchor the implantable valve to the wall of the bodily passage.

59. (Previously Presented) An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the plurality of legs terminating at a second end of the implantable valve opposite the first end such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction and seal against one another to restrict fluid flow in said second direction; and

wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane; and

wherein the covering includes two leaflets such that when the frame in the generally flat configuration generally assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.

60. (Currently Amended) A bi-leaflet valve prosthesis for implantation in a blood vessel, comprising:

a support frame including a plurality of bends and interconnected sides, the support frame having a first configuration for intravascular delivery into the blood vessel and a second configuration for implantation therein; a pair of opposing leaflets, each leaflet having an inner edge and an outer edge;

wherein the inner edges of the opposing leaflets are cooperable with one another to permit blood flow in a first direction within the vein, while restricting blood flow in a second direction opposite the first direction; and

wherein the outer edge of each of the plurality of leaflets is attached to at least one of the plurality of interconnected side elements such that the plurality of outer edges engage the walls of the bodily passage and collectively form a seal thereagainst along a pathway defined by the plurality of interconnected side elements;

wherein the outer edge of each of the plurality of leaflets includes an amount wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said side element; and

wherein the prosthesis includes at least one barb to anchor the prosthesis to a wall of the bodily passage.

61. (Currently Amended) The valve prosthesis of claim 55 wherein the plurality of leaflets comprise a bioremodelable material.

62. (Previously Presented) The valve prosthesis of claim 61 wherein the plurality of leaflets comprise an extracellular collagen matrix.

63 (Previously Presented) The valve prosthesis of claim 60, wherein the leaflets form a curved structure for trapping fluid between the plurality of leaflets and the inner wall of the blood vessel in response to fluid flow in the second direction so as to restrict the flow passing through the valve prosthesis in the second direction.

64. (Currently Amended) The valve prosthesis of claims 60, wherein the plurality of bends include at least a first bend and a second bend located about the first end of the prosthesis, the first bend and the second bend interconnecting two of the plurality of interconnected sides, each of the two interconnected sides extending a least partially longitudinally from the first bend and the second bend toward the second end of the prosthesis; and wherein the inner edges of the plurality of leaflets each include a first end and a second end, each of the first and second ends being carried about at least one of the first bend and the second bend.

65. (Previously Presented) The valve prosthesis of claim 64, wherein the first bend and the second bend each carry one of the first end or the second end of each of the plurality of leaflets.

66. (New) A bi-leaflet vascular valve prosthesis, comprising:

a support frame including a plurality of bends and interconnected side elements, the support frame having a first configuration for intravascular delivery and a second configuration for implantation in a vascular vessel;

the plurality of bends including a first bend and a second bend, wherein the first bend and the second bend are adapted to be positioned opposite one another when the support frame is in the second configuration;

a first leaflet and a second leaflet providing a bi-leaflet valve configuration having a valve orifice extending in a direction between the first bend and the second bend;

the first leaflet having a first outer edge portion attached extending along a side element connected to said first bend, and a second outer edge portion attached extending along a side element connected to the second bend; and

the second leaflet having a first outer edge portion attached extending along a side element connected to the first bend and a second outer edge portion attached extending along a side element connected to the second bend;

wherein each of said outer edge portions is wrapped around a corresponding side element to which the outer edge portion is attached so as to provide an amount of material occurring on an outer side of said corresponding leg; and

wherein said prosthesis includes at least one barb to anchor the prosthesis to a vascular vessel.

67. The bi-leaflet valve of claims 66, wherein the first leaflet and the second leaflet each include an inner edge having a first end connected to the first bend and a second end connected to the second bend.